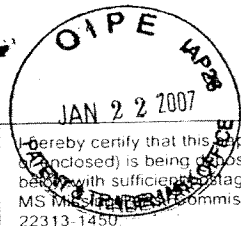


## **Exhibit B**




LAP13 Rec'd PCT/PTO 22 JAN 2007

PCT

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below, with sufficient postage as First Class Mail, in an envelope addressed to: MS M. R. McMillian, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: January 19, 2007

Signature

  
(Nabeeta R. McMillian)

Docket No.: 30986/40924  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Martin A. Crockard et al.

Application No.: 10/570,588

Filed: March 3, 2006

For: Diagnosis of Risk of Breast Cancer

Confirmation No.: 7390

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

**RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION**

MS Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice to File Missing Parts of Application – Filing Date. Granted mailed November 22, 2006, Applicant respectfully submits a Combined Declaration and Power of Attorney, a Sequence Listing Diskette, a Sequence Listing Paper Copy, and Part 2 Copy of Notice.

Our check in the amount of \$130.00 covering the fee set forth in 37 CFR 1.16(f) is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper

01/24/2007 ATRAN1 00000085 10570588

01 FC:1617

130.00 0P

Application No.: 10/570,588

Docket No.: 30986/40924

hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 30986/40924. A duplicate copy of this paper is enclosed.

Dated: January 19, 2007

Respectfully submitted,

By 

Nabeela R. McMillian

Registration No.: 43,363

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant

USA

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of subject matter which is claimed and for which a patent is sought on an invention entitled  
**DIAGNOSIS OF RISK OF BREAST CANCER**

the specification of which ☐ is attached hereto or

☐ was filed on 2 SEP 04 as United States Application Number or PCT International Application  
Number PCT/GB04/03773 and was amended on (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for a patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed:

| Prior Foreign<br>Application Number(s) | Country | Foreign Filing Date | Priority<br>Not Claimed  | Certified Copy<br>Attached? |                          |
|--|---------|---------------------|--------------------------|-----------------------------|--------------------------|
|  |         |                     |                          | YES                         | NO                       |
| 0320648.9                              | GB      | 3 SEP 03            | <input type="checkbox"/> | <input type="checkbox"/>    | <input type="checkbox"/> |
|  |         |                     | <input type="checkbox"/> | <input type="checkbox"/>    | <input type="checkbox"/> |
|  |         |                     | <input type="checkbox"/> | <input type="checkbox"/>    | <input type="checkbox"/> |

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Direct all correspondence to:  
Marshall, Gerstein & Borun  
6300 Sears Tower  
233 South Wacker Drive  
Chicago  
Illinois  
60606-6357  
United States of America

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C 1001 and that such willful false statements may jeopardise the validity of the application or any patent issued thereon.

Full name of sole or First Inventor Martin Andrew CROCKARD

Inventor's signature



Residence address Co. Antrim, BT29 4QY, Northern Ireland.

Post Office address

Radox Laboratories Ltd. Ardmore, Diamond Road, Crumlin  
Co. Antrim, BT29 4QY, Northern Ireland.

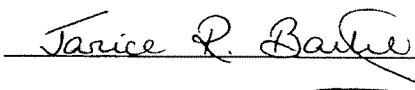
Country of Citizenship United Kingdom

Date of signature 16-05-06

Full name of Second Inventor

Janice Roberta BAILIE

Inventor's signature



Residence address Co. Antrim, BT29 4QY, Northern Ireland.

Post Office address

Radox Laboratories Ltd. Ardmore, Diamond Road, Crumlin  
Co. Antrim, BT29 4QY, Northern Ireland.

Country of Citizenship United Kingdom

Date of signature

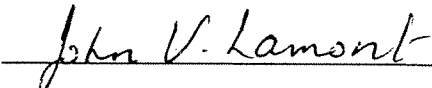
29<sup>th</sup> March 2006 6.5.06

Full name of

Third Inventor

John Victor LAMONT

Inventor's signature



Residence address Co. Antrim, BT29 4QY, Northern Ireland.

Post Office address

Radox Laboratories Ltd. Ardmore, Diamond Road, Crumlin  
Co. Antrim, BT29 4QY, Northern Ireland.

Country of Citizenship United Kingdom


Date of signature

29<sup>th</sup> March 2006

Full name of  
Fourth Inventor

Stephen Peter FITZGERALD

Inventor's signature



Residence address

Co. Antrim, BT29 4QY, Northern Ireland.

Post Office address

Randox Laboratories Ltd. Ardmore, Diamond Road, Crumlin  
Co. Antrim, BT29 4QY, Northern Ireland.

Country of Citizenship

United Kingdom

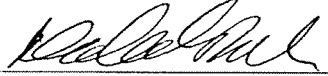
Date of signature

15.5.06

**PATENT**

Attorney Docket No.: 30986/40924

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                                    |   |  |
|------------------------------------|---|--|
| Inventors: Crockard et al.         | ) | I hereby certify that this paper is being  |
|                                    | ) | deposited with the United States Postal  |
| Serial No: 10/570,588              | ) | Service as first class mail, postage prepaid,                                      |
|                                    | ) | in an envelope addressed to Mail Stop  |
| Filed: March 3, 2006               | ) | Missing Parts, Commissioner for Patents,   |
|                                    | ) | P.O. Box 1450, Alexandria, VA 22313-   |
| Title: Diagnosis of Risk of Breast | ) | 1450 on  |
| Cancer                             | ) |  |
|                                    | ) |  |
| Group Art Unit: Not Yet Assigned   | ) | DATE: January 19, 2007   |
|                                    | ) |  |
| Examiner: Not Yet Assigned         | ) |  |
|                                    | ) | Nabeela R. McMillian   |
|                                    | ) |  |
|                                    | ) |  |

**STATEMENT UNDER 37 C.F.R. §§1.821(f)**


Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I hereby state that the content of the paper and computer-readable copies of the Sequence Listing, submitted herewith in accordance with 37 C.F.R. §§1.821 and 1.825, are the same and include no new matter.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN LLP  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606  
(312) 474-6300

By:   
Name: Nabeela R. McMillian  
Registration No.: 43,363  
Attorney for Applicants

Date: January 19, 2007

# SEQUENCE LISTING

<110> Randox Laboratories Ltd.

<120> Diagnosis of Risk of Breast Cancer

<130> 30986/40924

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<141> 2006-03-03

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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: January 19, 2007

Signature: 

(Nabeela R. McMillian)

Docket No.: 30986/40924  
(PATENT)



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Martin A. Crockard et al.

Application No.: 10/570,588

Confirmation No.: 7390

Filed: March 3, 2006

Art Unit: Not Yet Assigned

For: Diagnosis of Risk of Breast Cancer

Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an

Application No.: 10/570,588

Docket No.: 30986/40924

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 13-2855, under Order No. 30986/40924. A duplicate copy of this paper is enclosed.

Dated: January 19, 2007

Respectfully submitted,

By 

Nabeela R. McMillian

Registration No.: 43,363

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant

Form PTO-1449 (Modified)

## INFORMATION DISCLOSURE STATEMENT

Atty. Docket No.  
30986/40924Serial No.  
10/570,588Applicant(s)  
Martin A. Crockard et al.Filing Date  
March 3, 2006Art Unit  
Not Yet  
Assigned

## U.S. PATENT DOCUMENTS

| Examiner<br>Initials | Document<br>Number | Issue or<br>Publication Date | Name | Class | Subclass | Filing Date<br>(If Appropriate) |
|----------------------|--------------------|------------------------------|------|-------|----------|---------------------------------|
|                      |                    |                              |      |       |          |                                 |

## FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials | Document<br>Number | Publication<br>Date | Country | Translation |    |
|----------------------|--------------------|---------------------|---------|-------------|----|
|                      |                    |                     |         | Yes         | No |
|                      | WO 01/92581 A2     | 12/06/2001          | PCT     | X           |    |
|                      | WO 02/092854 A2    | 11/21/2002          | PCT     | X           |    |
|                      | WO 03/061386 A1    | 07/31/2003          | PCT     | X           |    |

## OTHER DOCUMENTS

|  |  |
|--|--|
|  | NCBI Sequence Viewer v2.0; Search Nucleotide; Authors: B. Birren et al.;<br>Website: <a href="http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&amp;val=24416019">http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&amp;val=24416019</a> ;<br>Dated: March 10, 2006                                |
|  | Article: Exploring the Metabolic and Genetic Control of Gene Expression on a Genomic Scale; Authors: Joseph L. DeRisi et al. Science Mag.-Vol. 278; Dated October 24, 1997<br>Website: <a href="http://www.sciencemag.org">www.sciencemag.org</a>  |
|  | Article: Differential Display of Eukaryotic Messenger RNA by Means of the Polymerase Chain Reaction; Authors: Peng Liang et al.; Science, New Series, Vol. 257, No. 50721; Dated August 14, 1992; pp. 967-971; Website: <a href="http://www.jstor.org">http://www.jstor.org</a>  |
|  | Clinical Chemistry 48:8 pp. 1147-1150 (2002); Cancer Diagnostics: Overview; Cancer Biomarkers: Easier Said Than Done; Author: Kenneth P. H. Pritzker   |
|  | Gene expression patterns of breast carcinomas distinguish tumor subclasses with clinical Implications; Authors: Therese Sorlie et al.; PNAS; September 11, 2001; Vol. 98; No. 19; pp. 10869-10874; Website: <a href="http://www.pnas.org/cgi/doi/10.1073/pnas.191367098">www.pnas.org/cgi/doi/10.1073/pnas.191367098</a> |

EXAMINER:

DATE CONSIDERED:

Form PTO-1449 (Modified)

**INFORMATION DISCLOSURE STATEMENT**Atty Docket No  
30986/40924Serial No.  
10/570,588Applicant(s)  
Martin A. Crockard et al.Filing Date  
March 3, 2006Art Unit  
Not Yet  
Assigned

Clinical Chemistry 48:8 pp 1160-1169; Vol.13, No. 3(2002); Cancer Diagnostics: Review; Proteomics for Cancer Biomarker Discovery; Authors: Pothur R. Srinivas et al.

Clinical Microbiology Reviews; Dated: July 2000; pp. 408-427; Copyright © 2000, American Society for Microbiology: Applications of Differential-Display Reverse Transcription-PCR to Molecular Pathogenesis And Medical Mycology

Clinical Chemistry 48:8; pp 1241-1250 (2002); Cancer Diagnostics: Discovery and Clinical Applications; Human Kallikrein gene 5 (KLK5) Expression by Quantitativr PCR: An Independent Indicator of Poor Prognosis In Breast Cancer: Authors: George M. Yousef et al.

Proc. Natl. Acad. Sci. USA; Vol. 96, pp. 10632-10636; September 1999; Biochemistry: Messenger RNA translation state: The second dimension of high-throughput expression Screening: Authors: Qin Zong et al.

EXAMINER:

DATE CONSIDERED:



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

|                             |                       |                  |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/570,588                  | Martin A. Crockard    | 30986/40924      |

04743  
 MARSHALL, GERSTEIN & BORUN LLP  
 233 S. WACKER DRIVE, SUITE 6300  
 SEARS TOWER  
 CHICAGO, IL 60606

RECEIVED

DEC 07 2006

COPY

MARSHALL GERSTEIN

|                               |
|-------------------------------|
| INTERNATIONAL APPLICATION NO. |
|-------------------------------|

PCT/GB04/03773

|                  |               |
|------------------|---------------|
| I.A. FILING DATE | PRIORITY DATE |
| 09/02/2004       | 09/03/2003    |

CONFIRMATION NO. 7390

371 FORMALITIES LETTER



\*OC000000021327992\*

Date Mailed: 11/22/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/03/2006
- Copy of the International Search Report filed on 03/03/2006
- Copy of IPE Report filed on 03/03/2006
- Preliminary Amendments filed on 03/03/2006
- Biochemical Sequence Listing filed on 03/03/2006
- U.S. Basic National Fees filed on 03/03/2006
- Priority Documents filed on 03/03/2006
- Specification filed on 03/03/2006
- Claims filed on 03/03/2006
- Abstracts filed on 03/03/2006
- Drawings filed on 03/03/2006
- Paper nucleotide sequence listings filed on 03/03/2006

Docketed: 1-22-07

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is **\$130** for a Large Entity:

- **\$130 Surcharge.**
- This application does not contain a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Applicant must provide such statement. If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)**

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

FREDERICK SMITH

---

Telephone: (703) 308-9140 EXT 210

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/570,588                  | PCT/GB04/03773                | 30986/40924      |

FORM PCT/DO/EO/905 (371 Formalities Notice)